

AMENDMENTS TO THE CLAIMS

This listing of the claims replaces all prior versions and listings of the claims for this application. Within this listing of the claims, the following changes have been made: claims 1, 20 and 23-28 have been amended and claims 41-44 are new. Claims 3, 4, and 15 were previously canceled and claims 16-19 and 29-40 were previously withdrawn as drawn to non-elected subject matter. Deletions to the claims are indicated with strikethroughs or with bold double brackets and additions to the claims are underlined.

1. **(Currently amended)** A method for treating sexual dysfunction in a female individual, comprising topically administering to the vagina and/or vulvar region of the individual a pharmaceutical formulation that comprises a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and an androgen polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof.

2. **(Original)** The method of claim 1, wherein the pharmaceutical formulation further includes a pharmaceutically acceptable carrier suited to vaginal and/or vulvar drug administration.

3-4. **(Canceled)**

5. **(Original)** The method of claim 1, wherein the pharmaceutical formulation further includes a compound selected from the group consisting of steroid agonists, partial agonists and antagonists.

6. **(Original)** The method of claim 1, wherein the pharmaceutical formulation is contained within a delivery system selected to provide a predetermined agent release profile.

7. **(Original)** The method of claim 6, wherein the agent release profile is pulsatile.

8. **(Original)** The method of claim 6, wherein the agent release profile is continuous.

9. **(Original)** The method of claim 6, wherein the agent release profile is cyclical.

10. **(Original)** The method of claim 6, wherein the agent release profile is diurnal.

11. **(Original)** The method of claim 1, wherein the pharmaceutical formulation is administered vaginally.

12. **(Original)** The method of claim 11, wherein the pharmaceutical formulation is in the form of an ointment, cream, gel, solid, solution, suspension, foam or liposomal composition.

13. **(Original)** The method of claim 11, wherein the pharmaceutical formulation is contained within a vaginal ring, tampon, suppository, sponge, pillow, puff, or osmotic pump system.

14. **(Original)** The method of claim 1, wherein the pharmaceutical formulation is administered to the vulvar region.

15. **(Canceled)**

16. **(Withdrawn)** The method of claim 1, wherein the vasoactive agent is a vasoactive intestinal polypeptide agonist.

17. **(Withdrawn)** The method of claim 16, wherein the vasoactive intestinal polypeptide agonist comprises a polypeptide sequence comprising a human vasoactive intestinal polypeptide sequence having amino acid substitutions at one or more positions.

18. **(Withdrawn)** The method of claim 17, wherein the vasoactive intestinal polypeptide agonist is terminally modified.

19. **(Withdrawn)** The method of claim 16, wherein the vasoactive intestinal peptide agonist comprises at least one agonist selected from the group consisting of SEQ. ID. NOS.:2-205 inclusive.

20. **(Currently amended)** The method of claim [[4]] 42, wherein the steroid is an androgenic agent.

21. **(Original)** The method of claim 20, wherein the androgenic agent is selected from the group consisting of androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, 4-dihydrotestosterone, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, methyltestosterone, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testolactone, testosterone, and pharmaceutically acceptable esters of testosterone and 4-dihydrotestosterone.

22. **(Original)** The method of claim 21, wherein the androgenic agent is selected from the group consisting of testosterone, C-17 esters of testosterone, 4-dihydrotestosterone, C-17 esters of 4-dihydrotestosterone, dehydroepiandrosterone, and methyltestosterone.

23. **(Currently amended)** A method for enhancing sexual desire and responsiveness in a female individual, comprising administering to the individual, approximately 0.25 to 72 hours prior to sexual activity, a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and a steroid polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof.

24. **(Currently amended)** A method for ~~maintaining~~ improving the tissue health of the female genitalia, comprising administering to a female individual, on an as-needed basis, a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and an androgen polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof.

25. **(Currently amended)** A method for preventing vaginal atrophy, comprising administering to a female individual, on an as-needed basis, a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and an androgen polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof.

26. **(Currently amended)** A method for preventing vaginal pain during sexual intercourse, comprising administering to a female individual suffering from dyspareunia a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and an androgen polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof.

27. **(Currently amended)** A method for alleviating vaginal itching and dryness, comprising administering to a female individual in need of such treatment a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and an androgen polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof.

28. **(Currently amended)** A method for enhancing sexual desire and responsiveness in a female individual, comprising administering a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and an androgen polypeptides, vasoactive intestinal polypeptide agonists, and combinations thereof to the individual in an amount effective to provide a blood level of the agent or a metabolite thereof that approximates the blood level of the agent or a metabolite thereof during ovulation.

29. **(Withdrawn)** A pharmaceutical formulation for enhancing female sexual desire and responsiveness, comprising (a) approximately 1.0 µg to 1.0 g of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide, agonists thereof, and combinations thereof, per gram of formulation, (b) a pharmaceutically acceptable carrier suitable for vaginal and/or vulvar administration..

30. **(Withdrawn)** The formulation of claim 29, wherein the formulation comprises approximately 50 µg to about 500 mg of the vasoactive agent per gram of formulation.

31. **(Withdrawn)** The formulation of claim 30, wherein the formulation comprises approximately 1.0 mg to about 250 mg of the vasoactive agent per gram of formulation.

32. **(Withdrawn)** The formulation of claim 29, wherein the carrier is selected to provide immediate release of the vasoactive agent from the formulation following application to the

individual's vagina and/or vulvar area, such that the formulation may be effectively administered on an on-demand basis.

33. **(Withdrawn)** The formulation of claim 29, comprising a gel, cream, ointment, solution or lotion.

34. **(Withdrawn)** The formulation of claim 29, comprising a suppository.

35. **(Withdrawn)** The formulation of claim 29, wherein the vasoactive agent is vasoactive intestinal polypeptide.

36. **(Withdrawn)** The formulation of claim 29, wherein the vasoactive agent is a vasoactive intestinal polypeptide agonist.

37. **(Withdrawn)** The formulation of claim 36, wherein the vasoactive intestinal polypeptide agonist comprises a polypeptide sequence comprising a human vasoactive intestinal polypeptide sequence having amino acid substitutions at one or more positions.

38. **(Withdrawn)** The formulation of claim 37, wherein the vasoactive intestinal polypeptide agonist is terminally modified.

39. **(Withdrawn)** The formulation of claim 36, wherein the vasoactive intestinal peptide agonist comprises at least one agonist selected from the group consisting of SEQ. ID. NOS.:2 - 205 inclusive.

40. **(Withdrawn)** A packaged kit for a female individual to use in enhancing sexual desire and responsiveness, comprising: a pharmaceutical formulation of a vasoactive agent selected from the group consisting of vasoactive intestinal polypeptide and agonists thereof; a container housing the pharmaceutical formulation during storage and prior to administration; and instructions for carrying out drug administration to enhance sexual desire and responsiveness.

41. **(New)** The method of claim 1, wherein the topically administered vasoactive agent is administered transmucosally.

42. **(New)** The method of claim 1, further including administering a steroid to the vagina and/or vulvar region of the individual.

43. **(New)** The method of claim 42, wherein the steroid is selected from the group consisting of progestins, estrogens, androgens, and combinations thereof.

44. **(New)** The method of claim 1, wherein the vasoactive agent is a vasoactive intestinal polypeptide.